IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

STATE OF DELAWARE, *ex rel.* MATTHEW P. DENN, ATTORNEY GENERAL, Plaintiff, v. PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; ANDA PHARMACEUTICALS, INC.; H.D. SMITH, LLC; CVS HEALTH CORPORATION; and WALGREENS BOOTS ALLIANCE, INC., Defendants.	)	C.A. No. 1:18-cv-00383-RGA

REMOVING DEFENDANT McKESSON CORPORATION'S OPPOSITION TO MOTION TO REMAND

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NATURE AND STAGE OF PROCEEDINGS

Defendant McKesson Corporation ("McKesson") removed this case because Delaware ("Plaintiff") raised claims that it had breached duties arising solely under the federal Controlled Substances Act, 21 U.S.C. §§ 801, *et seq.* (the "CSA"). (D.I. 1). Plaintiff moves to remand this case to state court for lack of subject matter jurisdiction even though its claims are predicated entirely on alleged violations of federal law by McKesson and other prescription opioid distributors (collectively, "Distributors"). (D.I. 4). McKesson opposes Plaintiff's remand motion because Plaintiff's reliance on federal law creates federal question jurisdiction under 28 U.S.C. § 1331.

PRELIMINARY STATEMENT

1. There are two separate and independent reasons why federal question jurisdiction is proper, but ultimately this Court need not and should not reach the merits of Plaintiff's motion.

2. *First*, the Complaint facially pleads a federal cause of action under the CSA. Plaintiff specifically cites to federal law throughout the Complaint to support its allegations, and even where Plaintiff purports to rely on state law, the centerpiece of alleged liability remains Distributors' alleged violation of duties arising solely out of the federal CSA. Without those federal duties, Plaintiff would fail to state a cause of action. Plaintiff therefore necessarily pleads a private cause of action under the federal CSA.

3. *Second*, federal jurisdiction is proper under the Supreme Court's four-part test set forth in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005), and *Gunn v. Minton*, 568 U.S. 251 (2013). Under that test, "federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. at 258. Here, all four factors are present: (1) Plaintiff's complaint necessarily

raises a federal issue, namely, the scope of Distributors' alleged duties under the CSA and Distributors' alleged violation of any such duties; (2) the parties actually dispute the federal issue because they contest whether Distributors violated the CSA; (3) the federal issue is substantial given the federal interest in the CSA's nationwide regulatory scheme, which requires uniformity, and the federal government's asserted interest in the subject matter of this litigation; and (4) federal jurisdiction will not upset any federal-state balance.

4. Although there is no basis for remand of this action to state court, this Court should defer consideration of Plaintiff's Motion to Remand and allow the issues presented therein to be decided on a national basis alongside almost identical claims brought by other attorneys general, cities, and counties across the country as part of the national opioid litigation that has been consolidated by the Judicial Panel on Multidistrict Litigation ("JPML") for pre-trial purposes in the United States District Court for the Northern District of Ohio (the "MDL").

5. For these reasons, the Court should deny Plaintiff's Motion to Remand and its request for expedited consideration.

BACKGROUND[1]

A. Plaintiff's Action

Plaintiff filed this lawsuit in Superior Court in January 2018 against three discrete sets of defendants: (i) Distributors, which are pharmaceutical wholesale distributors; (ii) pharmaceutical manufacturers, which make and promote opioid medications; and (iii) retail pharmacies, which fill prescriptions for opioid medications. Compl. ¶¶ 20-34.

[1] "JPML D.I." refers to the JPML's docket in *In re Nat'l Prescription Opiate Litig.*, MDL No. 2804 (J.P.M.L.), and "D.I." refers to this Court's docket in *Delaware v. Purdue Pharma L.P., et al.*, No. 1:18-cv-00383-RGA (D. Del.).

Plaintiff's central theory of liability against Distributors is that they allegedly violated two duties aimed at preventing "diversion" of controlled substances: a duty to implement effective controls to detect and report "suspicious" orders for controlled substances and a duty to halt shipments of suspicious orders.

Indeed, all of Plaintiff's claims against Distributors rest on allegations that Distributors should have reported and then refused to ship purportedly suspicious opioid orders from Delaware pharmacies. Plaintiff pleads that the opioids that Distributors "allowed to flow into Delaware [were] far in excess of what could be consumed for medically-necessary purposes." Compl. ¶ 160. Plaintiff further pleads that these "shipments should have been stopped or investigated as suspicious orders" and that Distributors thereby violated a duty to "control their supply lines to prevent diversion." *Id.* ¶¶ 159, 161. Plaintiff further attributes the prevalence of opioid abuse and misuse in Delaware to the "consistent failure [of defendants] to comply with their legal obligations," including Distributors' reporting and shipping requirements. Compl. ¶¶ 13-14.

Both alleged duties on which Plaintiff relies—the duty to report suspicious orders and the duty to halt shipments—find their source in federal law, specifically, the CSA. The alleged duty to implement effective controls to detect and report suspicious orders is set forth in the CSA's implementing regulations, as the Complaint itself acknowledges. *See* Compl. ¶ 108 (citing 21 C.F.R. § 1301.74). The alleged duty to halt shipments likewise arises out of the Drug Enforcement Administration's ("DEA") interpretation of the CSA, pursuant to which Distributors must "decline to ship" suspicious orders for controlled substances. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017) (citing *Southwood Pharm., Inc., Revocation of Registration*, 72 Fed. Reg. 36,487, 36,501 (July 3, 2007)).

Although Delaware has adopted the Uniform Controlled Substances Act, that act and its implementing regulations contain no comparable requirements to report and halt suspicious orders. Most relate instead to recordkeeping or warehouse security; none involves Distributors' fulfillment of orders. As the chart below indicates, Plaintiff's references to state-law duties do not support any cause of action that depends on over-distribution of opioids into Delaware:

Delaware Statute or Regulation	**Distributors' Legal Duties**	**Distributors' Duties Do Not Support Plaintiff's Claims**
16 *Del. C.* § 4732	Distributors "must obtain biennially a registration issued by the Secretary in accordance with the Secretary's rules." *See* Compl. ¶ 104.	Plaintiff alleges no specific violation of this statute; Distributors have maintained their registrations; and, in any event, no violation could support a claim of over-distribution.
24 *Del. Admin. C.* §§ 2500-8.5.2.2, 2500-8.5.2.4	Distributors must "[m]aintain records of sources of the drugs, the identity and quantity of the drugs received and distributed or disposed of, and the date of receipt and distribution or other disposition of the drugs" and "have records available for inspection and photocopying by the authorized federal, state, or local law enforcement agency officials for a period of three (3) years following the disposition of the drugs." *See* Compl. ¶ 164-66	This regulation is not a suspicious order reporting regulation, and the alleged violation of not responding to the State's November 2017 record request, Compl. ¶¶ 164-68, even if proven, has no causal relationship to Plaintiff's claims of over-distribution of opioids into Delaware.
24 *Del. Admin. C.* § 2500-8.6	Distributors shall "establish, maintain, and adhere to written policies and procedures for: identifying, recording, and reporting losses or thefts." *See* Compl. ¶ 105.	Plaintiff alleges no specific violation of this regulation, which requires a procedure for the reporting of thefts that a distributor experiences; this regulation is not a suspicious order reporting regulation; and, in any event, no violation could support a claim of over-distribution.
24 *Del. Admin. C.* § 2500-8.6.4	Distributors must maintain "[a] procedure for reporting criminal or suspected criminal activities	Plaintiff alleges no specific violation of this regulation, a subsection of the theft regulation above, that relates only to ***inventory*** in the possession of Distributors

	involving the inventory of a drug or drugs." *See* Compl. ¶ 105.	and not to fulfillment of orders placed by pharmacies. This regulation is not a suspicious order reporting regulation; and, in any event, no violation could support a claim of over-distribution.

B. The Multidistrict Litigation

Not only does Plaintiff base its claims on federal law, but these claims are the same as those being asserted in federal court by hundreds of other government entities against pharmaceutical manufacturers, distributors, and pharmacies relating to the sale, marketing, and distribution of prescription opioid medications.

To consolidate these cases for coordinated pre-trial proceedings, the JPML formed an MDL in December 2017 and initially transferred more than 60 opioid-related actions to Judge Dan A. Polster in the Northern District of Ohio, JPML D.I. No. 328. Since then, the JPML has transferred hundreds more actions to the MDL. *See* D.I. 15, at n.4.

After removing this action, Defendants tagged the case for inclusion in the MDL, and on March 14, the JPML issued an order conditionally transferring the case to the MDL on the ground that it appears to "involve questions of fact that are common to the actions previously transferred to the [MDL]." JPML D.I. No. 907 (CTO-16) (attached as Ex. 1).

The JPML has not yet made a final transfer decision because Plaintiff opposes transfer to the MDL. JPML D.I. No. 976. The JPML accordingly stayed its order conditionally transferring this case to the MDL, and the parties will submit briefs supporting and opposing transfer.

ARGUMENT

Given Plaintiff's reliance on duties arising exclusively under federal law, federal question jurisdiction is proper for two reasons. *First*, Plaintiff facially pleads a federal cause of action under the CSA. *Second*, to the extent that Plaintiff asserts state law causes of actions predicated on

alleged violations of the CSA, those claims necessarily raise substantial federal issues that should be resolved in federal court. Accordingly, Plaintiff's Motion to Remand should be denied.

I. THE COMPLAINT FACIALLY PLEADS A FEDERAL CAUSE OF ACTION.

Federal district courts have removal jurisdiction over "any civil action brought in a State court of which the district courts of the United States have original jurisdiction," 28 U.S.C. § 1441(a), and original jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States," 28 U.S.C. § 1331.

"Whether a case 'arises under' federal law for purposes of § 1331" is governed by the "well-pleaded-complaint rule." *Holmes Grp., Inc. v. Vornado Air Circulation Sys.*, 535 U.S. 826, 830 (2002). Under this rule, "federal question jurisdiction only exists where an issue of federal law appears on the face of the complaint." *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 445–46 (3d Cir. 2003). "A single claim over which federal-question jurisdiction exists is sufficient to allow removal." *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 194 (2d Cir. 2005); *see Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 563 (2005); *City of Chicago v. Int'l Coll. of Surgeons*, 522 U.S. 156, 164–66 (1997).

Contrary to Plaintiff's assertion, Remand Mot. ¶¶ 14-15, the Supreme Court has called into question any artificial presumption against federal question jurisdiction. *See Breuer v. Jim's Concrete of Brevard, Inc.*, 538 U.S. 691 (2003) (strict construction against removal has been qualified by later statutory development); *Mims v. Arrow Fin. Servs., LLC*, 565 U.S. 368, 379 (2012) ("Divestment of district court jurisdiction should be found no more readily than divestment of state court jurisdiction, given the longstanding and explicit grant of federal question jurisdiction in 28 U.S.C. § 1331." (alterations and quotation marks omitted)).

A. Plaintiff's Claims Include Four Counts That Facially Plead Federal Law Violations.

In Counts V, VI, VII, and IX, Plaintiff specifically pleads that Distributors' failure to report or halt shipments of suspicious orders violated federal law. *See Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987) (federal jurisdiction exists when federal question is presented "on the face of the plaintiff's properly pleaded complaint"); *see Lontz v. Tharp*, 413 F.3d 435, 439 (4th Cir. 2005) (removal "is appropriate if the face of the complaint raises a federal question" (citations omitted)).

Because there are no such duties under Delaware law, Plaintiff unsuccessfully attempts to connect these alleged federal violations to state causes of action as follows:

- In Count V, Plaintiff alleges that Distributors violated the Delaware Consumer Fraud Act by misrepresenting or concealing violations of federal regulations by "habitually filling suspicious or invalid orders for prescription opioids" and by "failing to operate a system to disclose suspicious orders of controlled substances." Compl. ¶¶ 263-65.

- In Count VI, Plaintiff alleges that Distributors created a public nuisance by "failing to design and operate an adequate system to detect, halt, and report suspicious orders of controlled substances." *Id.* ¶ 268.

- In Count VII, Plaintiff alleges that Distributors were negligent by "inviting criminal activity into Delaware by disregarding precautionary measures built into the DE CSA and FCSA," by "failing to adhere to all applicable laws and regulations pertaining to the distribution and sale of prescription opioids," by "failing to report suspicious orders or refuse to fill them," and by "failing to police the integrity of the supply chain for prescription opioids." *Id.* ¶¶ 279-280.

- Finally, in Count IX, Plaintiff alleges that Distributors participated in a civil conspiracy when they "continuously supplied prescription opioids to Pharmacy Defendants . . . despite Distributor Defendants and Pharmacy Defendants having actual or constructive knowledge that they were habitually breaching their common law duties and violating the DE CSA and FCSA." *Id.* ¶ 304.

These claims also incorporate allegations outlining the applicable federal law and describing the federal CSA as "***the standard of conduct*** to which Distributor Defendants must adhere." *Id.* ¶ 106 (emphasis added).

Although Plaintiff correctly states that there is no private right of action under the federal CSA, Remand Mot. ¶ 24, so long as Plaintiff has put federal law at issue by predicating its claims on federal law duties, federal jurisdiction is proper. The lack of a private right of action under the CSA should doom Plaintiff's claims on the merits, but it does not doom federal jurisdiction. *See Grable*, 545 U.S. at 318-20 (lack of private right of action does not foreclose federal jurisdiction).

B. Token References To State Law Do Not Alter Plaintiff's Facial Pleading Of Federal Law.

Although a plaintiff "may avoid federal jurisdiction by *exclusive* reliance on state law," *Caterpillar*, 482 U.S. at 392 (emphasis added), Plaintiff's claims here necessarily rely on duties arising under federal law. The Complaint's passing references to state laws and regulations, which offer no support for Plaintiff's causes of action, do not allow Plaintiff to evade federal jurisdiction. *See Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 808 (1986) (a "suit arises under the law that creates the cause of action") (internal quotation marks and citations omitted).

Because Distributors have no duty to report, much less halt, suspicious opioid orders under the Delaware CSA or its implementing regulations, Plaintiff has no choice but to include the federal CSA in its Complaint so as to attempt to disguise the absence of comparable provisions in the Delaware CSA. *See* Compl. ¶ 94 ("Delaware and Federal laws and regulations impose duties on Distributor Defendants"), ¶ 106 ("***Like the DE CSA***, the FCSA sets the standard of conduct to which the Distributor Defendants must adhere") (emphasis added), *id.* ("Also ***like the DE CSA***, the FCSA requires all opioid distributors to maintain effective controls against opioid diversion and to employ a system to identify and report to law enforcement suspicious orders of controlled substances.") (emphasis added). Plaintiff likewise has no choice but to acknowledge its reliance on federal law throughout the Complaint. Remand Mot. ¶ 20.

Although Plaintiff attempts to pass off its reliance on federal law as "mere references," *id.* ¶ 22, designed to "help elucidate the standard of care . . . under state law," *id.* ¶ 23, it cannot evade the absence of a legal duty generated by state law. *See In re Microsoft Corp. Antitrust Litig.*, 127 F. Supp. 2d 702, 722 (D. Md. 2001) ("There is no evident purpose" for inclusion of federal law violations "unless plaintiffs contemplate the assertion of [federal] claims").

Plaintiff's reliance on *West Virginia v. McKesson Corporation*, Remand Mot. ¶ 22, only underscores the absence of analogous Delaware law duties by way of comparison to other states. In *McKesson*, the court's decision to remand relied on alleged violations of state law duties supported by citations to the West Virginia Code. *See West Virginia v. McKesson Corp.*, 2017 WL 357307, *4 (S.D. W. Va. Jan. 24, 2017); *id.* at *7 (citing West Virginia regulations requiring that registrants "design and operate a system to disclose to the registrant suspicious orders of controlled substances," as well as report suspicious orders to a state entity once discovered). In other words, West Virginia law imposes on distributors requirements related to monitoring and reporting suspicious orders.

That is not the case in Delaware, which merely requires reporting of "criminal or suspected criminal activities involving the *inventory* of a drug." 24 *Del. Admin. C.* § 2500-8.6.4 (emphasis added). This obligation to report theft of warehouse inventory is distinct from the obligation to report and halt "suspicious orders" placed by pharmacies, which arises only under the federal CSA.

II. THE COMPLAINT RAISES A SUBSTANTIAL FEDERAL QUESTION.

Even where state law creates the cause of action, a claim may raise a federal question sufficient to warrant removal jurisdiction. As noted, under the Supreme Court's *Grable* and *Gunn* decisions, "federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. at 258; *see also*

Grable, 545 U.S. at 315. "Where all four of these requirements are met . . . jurisdiction is proper because there is a 'serious federal interest in claiming the advantages thought to be inherent in a federal forum,' which can be vindicated without disrupting Congress's intended division of labor between state and federal courts." *Gunn*, 568 U.S. at 258 (quotation marks omitted).

Courts have found these factors to be satisfied in cases where state law claims are predicated on violations of federal statutes governing complex, nationwide regulatory schemes for which uniformity is essential. *See, e.g.*, *PNC Bank, N.A. v. PPL Elec. Util. Corp.*, 189 F. App'x 101, 104 n.3 (3d Cir. 2006) (state law claim based on violation of Internal Revenue Code "gives rise to federal-question jurisdiction" under *Grable*); *Broder*, 418 F.3d at 196 (state law claims premised on cable provider's alleged violations of Communication Act's uniform rate requirement satisfy "*Grable* test for federal-question removal jurisdiction"); *NASDAQ OMX Grp., Inc. v. UBS Sec., LLC*, 770 F.3d 1010, 1031 (2d Cir. 2014) (state law claims premised on violations of Exchange Act "necessarily raise disputed issues of federal law of significant interest to the federal system as a whole"); *New York ex rel. Jacobson v. Wells Fargo Nat'l Bank, NA*, 824 F.3d 308, 315–18 (2d Cir. 2016) (state law claims based on defendant's alleged violation of Internal Revenue Code satisfy *Grable*); *Ranck v. Mt. Hood Cable Regulatory Comm'n*, 2017 WL 1752954, at *5 (D. Or. May 2, 2017) (state law claims based on violations of Cable Communications Policy Act satisfy *Grable*).

This case, too, satisfies all four elements of *Grable* and *Gunn*.

A. The Federal Issue Is Necessarily Raised.

An action "necessarily raises" a federal question when "the right to relief depends upon the construction or application of federal law." *PNC Bank*, 189 F. App'x at 104 n.3. Significantly, "an action under 28 U.S.C. § 1331(a) arises . . . ***if the action requires construction of a federal statute***, or at least a distinctive policy of a federal statute requires the application of federal legal

principles." *V.I. Hous. Auth. v. Coastal Gen. Constr. Servs. Corp.*, 27 F.3d 911, 916 (3d Cir. 1994) (emphasis added); *see also Merrell Dow*, 478 U.S. at 808–09 (1986) (federal question jurisdiction exists if "vindication of a right under state law ***necessarily turn***[***s***] ***on some construction of federal law***" (emphasis added)).

In determining whether state law claims turn on construction or application of federal law, the Court must "begin by considering the duty underlying each claim." *NASDAQ*, 770 F.3d at 1020. "A state-law claim 'necessarily' raises federal questions where the claim is affirmatively 'premised' on a violation of federal law," *Jacobson*, 824 F.3d at 315, or where the "singular duty" underlying the claim arises under federal law, *NASDAQ*, 770 F.3d at 1021.

Here, Plaintiff's claims necessarily raise federal issues because they are "affirmatively premised" on Distributors' alleged violation of federal law, namely, the CSA. As pled, Plaintiff's claims are predicated on Distributors' alleged violation of alleged duties to monitor for, report, and halt suspicious orders for prescription opioids—duties that arise, if at all, exclusively under the CSA, its implementing regulations, and DEA rulings. *See*, *e.g.*, Compl. ¶¶ 263, 268, 280, 304; *see also* Compl. ¶ 96 (alleging that Distributors' purported "violations of . . . Federal laws and regulations show that they failed to meet relevant standard of care"); *id.* at ¶ 106 ("[T]he FCSA sets the standard of conduct to which Distributor Defendants must adhere."); *id.* at ¶ 203 (alleging that Distributors "violat[ed] their duties under . . . Federal law and regulations").

Although Plaintiff attempts to cast its reliance on federal law as one of many "alternative theories," Remand Mot. ¶ 30, it fails to acknowledge, as it must, that it is the *only* theory insofar as federal law is the sole possible source of the legal duties on which Plaintiff's claims depend. As discussed above, Plaintiff has not identified and cannot identify any corollary duty to report or halt opioid shipments under Delaware law. To succeed on its claims against Distributors, Plaintiff

would have to show that Distributors violated the CSA, which necessarily turns on construction and application of the CSA. *See Masters Pharm., Inc.* 861 F.3d at 212-13.

Plaintiff's claim for public nuisance (Count VI) illustrates the point. To establish that Distributors caused a public nuisance, Plaintiff must show, among other things, that Distributors' conduct was unreasonable or unlawful. *See, e.g., Town of Georgetown v. DeRiemer for DeReimer*, 1990 WL 80463, at *4 (Del. Ch. May 31, 1990). Plaintiff's theory that Distributors acted unreasonably or unlawfully is based on Distributors' distribution of opioids into Delaware. Compl. ¶ 268. Because Distributors are all registered with the DEA and the State to distribute controlled substances to registered pharmacies in Delaware, there is no basis to claim that their distribution was unlawful absent Plaintiff's attempt to apply federal CSA requirements that distributors report and halt "suspicious orders." Thus, to establish its public nuisance claim as pled, Plaintiff ***must*** show that Distributors violated the CSA, thereby raising a federal issue.

B. The Federal Issue Is Actually Disputed.

The federal issue raised by the Complaint is "actually disputed" for the simple reason that the parties contest whether Distributors violated the CSA and whether Plaintiff may assert claims for alleged violations of the CSA. Indeed, because all of Plaintiff's claims against Distributors depend on its theory that Distributors violated the CSA, this issue is the "central point of dispute." *Gunn*, 568 U.S. at 259.

Although Plaintiff does not disagree that the parties dispute whether Distributors violated the CSA, Plaintiff maintains, without basis, that a federal issue is "actually disputed" only if "there is a dispute over the meaning of the federal statute or regulation, not [if] there is a factual dispute over whether the defendant violated the statute or regulation." Remand Mot. ¶ 32.

As an initial matter, Plaintiff's argument rests on a false distinction between "interpreting" federal law and "applying" it. *See Tarrant v. Ponte*, 751 F.2d 459, 463 (1st Cir. 1985) ("[A]ny

attempted distinction between 'interpretation' and 'application' is elusive, unsupported by any authority, and would be, as a practical matter, impossible to implement."). The two tasks cannot be so easily divorced because, as other courts have recognized, "clearly many 'applications' of the law to a given set of facts entail either an express or implied interpretation of the law." *Henry v. Quicken Loans Inc.*, 2009 WL 3270771, at *18 (E.D. Mich. July 16, 2009).

The same holds true here. In assessing whether Distributors violated the CSA, the Court must determine not only the conduct of Distributors, but whether that conduct violated alleged duties arising under the CSA. That is, the Court must examine "the contours of [the] federal duty," "the scope of that duty," and "whether [Distributors' conduct] amounted to a breach of that duty." *NASDAQ*, 770 F.3d. at 1023. That will require the Court to determine what constitutes a "suspicious" delivery under the CSA's implementing regulations, what actions should have been taken to resolve those suspicious orders or "halt" the shipment, whether existing processes satisfy federal reporting guidelines, and other disputes arising under federal regulations.

Even if there were a salient and articulable distinction between interpretation and application and even if Plaintiff's claims did not require interpretation of the CSA, nothing in *Grable* or *Gunn* limits federal-question jurisdiction to disputes over interpretation of federal law. To the contrary, *Gunn* itself recognized that a federal issue is "actually disputed" where it requires "***application*** of [federal] patent law to the facts of [the] case." *Gunn*, 568 U.S. at 259. Other courts have similarly held that a dispute over whether a defendant violated federal laws is sufficient to satisfy the "actually disputed" prong. In *NASDAQ*, for example, the Second Circuit explained that a federal issue is "actually disputed" even where "there is no dispute . . . as to the ***existence*** of a federal duty" as long as "there is . . . a dispute as to the ***violation*** of that duty." 770 F.3d at 1021 (citation omitted, emphases in original).

C. The Federal Issues Are Substantial.

The federal issues here warrant federal jurisdiction because they are substantial, and the federal government has a strong interest in the CSA's uniform interpretation and application.

1. There is a federal interest in ensuring uniform interpretation of the CSA.

As the Supreme Court has explained, "[t]he substantiality inquiry under *Grable* looks . . . to the importance of the issue to the federal system as a whole," which includes, among other things, whether the federal government has a "strong interest" in the federal issue at stake and whether allowing state courts to resolve the issue will "undermine the development of a uniform body of [federal] law." *Gunn*, 568 U.S. at 260, 261-62 (quotation marks omitted). Exercising federal-question jurisdiction in such cases "captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Grable*, 545 U.S. at 312.

Applying this analysis, courts have found federal issues to be sufficiently substantial where they raise "questions [that] involve aspects of . . . complex federal regulatory scheme[s] . . . as to which there is a serious federal interest in claiming the advantages thought to be inherent in a federal forum." *Broder*, 418 F.3d at 195 (quotation marks omitted). Such rulings are especially common where, as here, federal agencies are responsible for implementing a national regulatory system for which uniformity is essential. In *NASDAQ*, for example, the Second Circuit ruled that "the disputed federal issue in th[e] case—whether [the defendant] violated its Exchange Act obligation to provide a fair and orderly market in conducting an IPO—is sufficiently significant to the development of a uniform body of federal securities regulation to satisfy the requirement of importance to the federal system as a whole." 770 F.3d at 1024 (quotation marks omitted).

Likewise, in *Jacobson*, the Second Circuit held that "minimizing uncertainty over the tax treatment of mortgage-backed securities, as Congress intended, fully justif[ied] resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." 824 F.3d at 318.[2]

Similarly, Plaintiff's claims would require this Court to determine the scope of Distributors' obligations under the CSA and whether Distributors breached those duties, implicating the uniformity concerns addressed above. In enacting the CSA, Congress stated that it was "providing the legitimate drug industry with a ***unified*** approach to narcotic and dangerous drug control." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4572 (emphasis added). Plaintiff's claims thus "involve aspects of the complex federal regulatory scheme applicable to" the national prescription drug supply chain, *Broder*, 418 F.3d at 195, and are "sufficiently significant to the development of a uniform body of [controlled substances] regulation to satisfy the requirement of importance to the federal system as a whole," *NASDAQ*, 770 F.3d at 1024 (quotation marks omitted). Furthermore, "minimizing uncertainty over" reporting and shipping obligations under the CSA "justifies resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Jacobson*, 824 F.3d at 317–18 (quotation marks and alteration omitted).

Resort to a federal forum is particularly warranted here because Plaintiff's action is but one of several hundred pending in the MDL. *See* D.I. 15, at 2-3. If this case is allowed to proceed in

[2] Plaintiff fails to identify any meaningful distinction between these Second Circuit cases and this case. Although Plaintiff asserts that *NASDAQ* involved a "unique situation in which the sole alleged duty consisted of allegations that" the defendant violated federal law, Remand Mot. ¶ 41, that is the same circumstance presented by this case: the sole alleged duty on which Plaintiff relies consists of allegations that Distributors violated the CSA. Similarly, that *Broder* involved a declaratory judgment action provides no grounds for distinction; there, like here, state law causes of action premised on violations of federal law necessarily raised substantial issues of federal law. *See Broder*, 418 F.3d at 196.

federal court and transferred to the MDL, the MDL court will be able to ensure uniform construction and application of the CSA, thus achieving Congress's goal of a "unified approach" to regulating controlled substances.

2. The federal government has expressed an interest in interpreting and applying the CSA in this litigation.

Although Plaintiff correctly notes that in assessing substantiality, the Court must consider "whether the issue will have a broad impact on the Federal Government," Remand Mot. ¶ 33, Plaintiff then wrongly asserts that resolving the federal issue here (*i.e.*, the scope of duties under the CSA and whether Distributors violated those duties) "will have no effect on the Federal Government" and "will not directly affect actions taken by federal actors," *id.* ¶ 34.

The federal government has made clear the effect that the opioid litigation will have on its ability to enforce the CSA. Most notably, earlier this month, the Department of Justice filed a Statement of Interest on behalf of the United States in the MDL proceedings, asserting the federal government's interests in, among other things, its "law enforcement and legal activities in conjunction . . . with the multidistrict litigation," specifically including "[c]riminal and civil tools available ***under the Controlled Substances Act***." *See S*tatement of Interest of the United States, *In re: National Prescription Opiate Litigation*, No. 1:17-md-02804 , ECF No. 161, at 7 (N.D. Ohio Mar. 1, 2018) (attached as Ex. 2) (emphasis added).

Allowing a state court to resolve state law claims premised on violations of the CSA—and to determine the scope of any duties under the CSA—creates the potential for inconsistent interpretations of the CSA across jurisdictions. *See* 21 U.S.C. § 903 (although Congress did not intend to "occupy the field" of controlled substances regulation with CSA, CSA pre-empts inconsistent state law). Conflicting interpretations of the CSA could undermine the federal government's efforts to enforce the statute.

3. Substantiality does not require a federal cause of action.

Similarly, Plaintiff's argument that the federal question cannot be substantial because the CSA does not create a private cause of action, Remand Mot. ¶¶ 33, 36 (citing *Merrell Dow*, 478 U.S. 804), does not comport with the law. In *Grable*, which was decided after *Merrell Dow*, the Supreme Court specifically held that lack of a federal cause of action does not foreclose federal-question jurisdiction. The Court stated that applying *Merrell Dow* too narrowly would both "overturn[ ] decades of precedent" and "convert[ ] a federal cause of action from a sufficient condition for federal-question jurisdiction into a necessary one." *Grable*, 545 U.S. at 317. Indeed, *Grable* itself found that the federal issue presented in that case was sufficiently substantial notwithstanding the lack of a federal cause of action. *See Broder*, 418 F.3d at 196 ("The *Grable* Court found this last requirement to be satisfied even in the absence of a private right of action[.]").

Thus, that the CSA does not afford Plaintiff a private right of action does not diminish the substantiality of the federal question here, particularly when federal courts have exclusive jurisdiction to enforce the CSA.

D. Congressionally Approved Federal-State Balance.

Finally, the federal issue presented by Plaintiff's action is capable of resolution in federal court "without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. at 258. Federal courts exclusively hear challenges to DEA authority to enforce the federal CSA against distributors.[3] Similarly, federal courts have exclusive jurisdiction over proceedings seeking to

[3] *See, e.g.*, *PDK Labs. Inc. v. U.S. Drug Enf't Admin.*, 362 F.3d 786 (D.C. Cir. 2004) (challenge to DEA program enforcing CSA to prevent diversion of ephedrine); *Admin. Subpoena Walgreen Co. v. U.S. Drug Enf't Admin.*, 913 F. Supp. 2d 243 (E.D. Va. 2012) (resolving registrant's motion to require DEA to return subpoenaed documents); *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012) (challenge under Administrative Procedure Act to DEA order suspending registration of distribution facility).

enjoin violations of the CSA. *See* 21 U.S.C. § 882(a) ("The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings . . . to enjoin violations of this subchapter.").[4] Thus, federal courts already are the exclusive forum for determining the permissible scope of restraints on Distributors under the federal CSA. Plaintiff's Complaint presents these precise questions.[5]

Plaintiff's citation to nonbinding, out-of-circuit district court decisions, Remand Mot. ¶ 38, does not compel a different result. Two of these decisions were decided before *Grable* and *Gunn*, and thus did not use the required four-factor analysis. *See Little v. Purdue Pharma, L.P.*, 227 F. Supp. 2d 838 (S.D. Ohio 2002); *McCallister v. Purdue Pharma, L.P.*, 164 F. Supp. 2d 783 (S.D. W. Va. 2001). Likewise, in *Brown v. Endo Pharm., Inc.*, 38 F. Supp. 3d 1312, 1320 (S.D. Ala. 2014), the court found that questions about the CSA were only "ostensibly implicated" by a plaintiff's complaint, whereas in this case Plaintiff's claims all depend exclusively on alleged CSA violations. Finally, as noted, *West Virginia v. McKesson* is distinguishable because, unlike West Virginia law, Delaware law does not provide for duties to report and halt suspicious orders.

III. BECAUSE THIS COURT SHOULD DEFER CONSIDERATION OF PLAINTIFF'S MOTION TO THE MDL COURT, EXPEDITED CONSIDERATION IS UNNECESSARY AND UNWARRANTED.

This Court should not only deny Plaintiff's request for expedited consideration as unnecessary and unwarranted, but also defer ruling on Plaintiff's motion altogether. Delaying consideration of remand until the JPML makes a final transfer decision will promote judicial

[4] Although the Complaint does not expressly seek to enjoin Distributors' alleged violations of the federal CSA, it does request "further relief as justice and equity may require," which may reasonably be read to include injunctive relief. *See* Compl. at pp. 114-17.

[5] Furthermore, as explained above, allowing cases like this one to proceed in federal court promotes uniform development of federal law. By contrast, litigating this case in state court runs the risk of the state court applying federal requirements inconsistently with the manner in which DEA—the federal agency responsible for enforcing the CSA—applies them.

efficiency and ensure consistent remand rulings by allowing the MDL Court to consider this and all other remand motions presenting similar issues. Plaintiff's arguments to the contrary proceed from the faulty premises that (i) a JPML decision transferring this case to the MDL is immediately forthcoming and (ii) if the case is transferred to the MDL, Plaintiff will be unduly prejudiced because Judge Polster does not intend to consider remand motions.

First, the JPML's timeline for making a final transfer decision is long enough to render expedited consideration unnecessary but short enough to avoid prejudice to Plaintiff. When Plaintiff objected to transfer, the JPML automatically stayed its conditional transfer order of this action and set a briefing schedule on transfer. JPML Dkt. Nos. 907, 976. The next available hearing is May 31, *see* Hearing Information, U.S. Judicial Panel on Multidistrict Litigation, http://www.jpml.uscourts.gov/hearing-information, and a decision would likely come a few weeks after the hearing. The JPML will make a final transfer decision as soon as this June. Therefore, there is no reason for this Court to rush consideration of these issues.

Second, if the case is transferred, there is no support for Plaintiff's assertion that Judge Polster will indefinitely delay consideration of remand. Although Plaintiff cites a December 2017 transcript from the first MDL teleconference during which Judge Polster stated that he would not immediately rule on remand motions, *see* Remand Mot. ¶¶ 11, 47, circumstances have changed. On March 7, Judge Polster indicated that he intends to issue a case management order that will contain, among other things, "timing of motion practice (including ***issues related to remand***)." *See* Minutes of 3/6/2018 Conference and Order, *In re: Nat'l Prescription Opiate Litig.*, No. 1:17-md-02804, ECF No. 170 (N.D. Ohio Mar. 7, 2018) (attached as Ex. 3) (emphasis added). Thus, contrary to Plaintiff's assertion, Judge Polster's Order indicates that he plans to consider remand motions in a reasonable fashion and can do so in a coordinated way to avoid inconsistent rulings.

Although Plaintiff also cites to a statement by Judge Polster indicating that he will not exercise jurisdiction over attorney general actions pending in state court as evidence that remand is appropriate, Remand Mot. ¶ 11, Judge Polster's statement merely recognizes the unremarkable proposition that a federal court does not have jurisdiction over state court cases that have not been properly removed to federal court and transferred to the MDL, *see* Case No. 17-MD-2804, Dkt. No. 146 (N.D. Ohio Feb. 27, 2018). Indeed, other state attorney general actions have been transferred or conditionally transferred to the MDL. *See* JPML D.I. No. 779 (Alabama); JPML D.I. 798 (Kentucky); JPML D.I. 835 (Montana).

Furthermore, not only does the MDL Court intend to rule on remand motions such as Plaintiff's, it is the court best positioned to do so. *See Little v. Pfizer, Inc.*, 2014 WL 1569425, at *3 (N.D. Cal. Apr. 18, 2014) (citation omitted) ("[C]ourts have repeatedly noted that the 'general rule is for federal courts to defer ruling on pending motions to remand in MDL litigation until after the [JPML] has transferred the case.'"). The jurisdictional issue presented by Plaintiff's remand motion is also likely to arise in other cases that have been tagged for inclusion in the MDL. *See, e.g.*, *City of Paterson v. Purdue Pharma L.P. et al.*, No. 2:17-cv-13433 (D.N.J. Dec. 20, 2017); *Kentucky v. McKesson Corp.*, No. 3:18-cv-00010 (E.D. Ky. Feb. 23, 2018). Therefore, in the interests of promoting judicial economy and consistency of rulings, this Court should defer consideration of Plaintiff's motion and instead allow the MDL Court to address it along with the others. *See In re Intel Corp. Microprocessor Antitrust Litig.*, 2008 WL 5156628, at *1 (D. Del. Dec. 5, 2008) ("A guiding principle of an MDL declaration is to attempt uniformity in case management and pretrial decisions in complex nationwide litigation.").

CONCLUSION

For the foregoing reasons, the motion to remand should be denied.

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